

Notice of Allowability

Application No.

10/817,312

Applicant(s)

PALMER ET AL.

Examiner

Art Unit

Anand U. Desai, Ph.D.

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview of 11/14/05.
2. ☒ The allowed claim(s) is/are 1-32, 34-48 and 50-72.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>11-14-05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Withdrawal of Rejections

1. The rejection of claims 1-7, 14-32, 34, 35, 37-39, 41-47, 50, 51, 54-56, 63, 64, 67, and 69 under the judicially created doctrine of obviousness-type double patenting over copending Application 10/498,639 is withdrawn.
2. The rejection of claims 1-7, 14-32, 34, 35, 37-39, 41-47, 50, 51, 54-56, 63, 64, 67, and 69 under the judicially created doctrine of obviousness-type double patenting over copending Application 10/014,812 is withdrawn.
3. The rejection of claims 1-7, 14-32, 34, 35, 37-42, 44-47, 50, 51, 54, 55-58, 62, and 63 under 35 U.S.C. 102(e) as being anticipated by Palmer et al. (U.S. 2002/0065324 A1) is withdrawn.
4. The rejection of claims 1-11, 14-32, 34, 35, 37-47, 50-59, and 62-65 under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. (U.S. 2002/0065324 A1) in view of Bowman, et al. is withdrawn.
5. The rejection of claims 66-72 under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. (U.S. 2002/0065324 A1) in view of Bowman et al. and further in view of Barbieri et al. is withdrawn.

EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Teddy C. Scott, Jr. on November 18, 2005.

Examiners' amendment to the Claims:

1. (Currently Amended) A method for stimulating ovarian follicular growth in a female, comprising administering to a female a medicament comprising a phosphodiesterase (PDE) inhibitor, whereby ovarian follicular growth is stimulated in said female.

Allowable Subject Matter

7. Claims 1-32, 34-48, and 50-72 are allowed.
8. The following is an examiner's statement of reasons for allowance: The reason for allowance of copending application 10/014,812 describes the state of the prior art; U.S. Patent 6,423,710 contains the motivation of using the PDE4 inhibitor for induction of ovulation, which is based on elevation of cAMP level by the inhibitor, within granulosa cells; 6,423,710 does not fairly teach or suggest inducing in vivo ovulation in a female host by administering to the host the PDE4 inhibitor. Additionally, applicants point out that assumption made by the Tsafirri that suppression of cAMP-specific PDE may enhance the gonadotropin induction of ovulation is only limited to in vitro studies. Applicants stress that Tsafirri does not teach in vivo application of the PDE inhibitory compound(s) to induce ovulation. (2) Before this invention, the field of PDE4 inhibitor confronts unpredictability, especially as to its roles in reproductive biology, e.g., Jin et al. reference has indicated that the PDE4 knockout exhibits an impaired ovulation (Proc. Natl. Acad. Sci. (1999) 96, 1 1998-12003, see Results, section Effects of the Disrupted PDE4D Gene on Female Fertility, and Figure 5A); and, on page 1324, Conti's Minireview reference (Mol.

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Endocrinol. (2000) 14, 1317-1327) has discussed that use of PDE indicators in endocrine cell responses (note that ovulation is one of such the responses) is an unexplored field. Therefore, the obviousness rejection based on 6,423,710 lacks a reasonable expectation of success, which is the standard with which obviousness is determined.

Applicants state that Palmer et al. (US 2002/0065324 A1) discloses in example 2 that increasing doses of PDE inhibitors failed to enhance the ability of sub-optimal dose of FSH to prepare follicles to ovulate and teaches away from the currently claimed invention (see paragraph [0086], last sentence).

Sher, G. and Fisch, J. describe the effect of sildenafil to improve uterine artery blood flow and estrogen-induced proliferation of the endometrial lining to enhance in vitro fertilization reproduction outcomes (see entire document; Fertility and Sterility Vol. 78, No. 5, pp. 1073-1076 (2002)).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 21, 2005



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER